EXHIBIT B

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

TORRENT PHARMACEUTICALS
LIMITED, INC., TORRENT PHARMA
INC., and HETERO LABS LIMITED,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

ALEMBIC PHARMACEUTICALS
LIMITED, ALEMBIC LIMITED,
ALEMBIC GLOBAL HOLDING SA, and
ALEMBIC PHARMACEUTICALS INC.,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LIMITED,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC,

Defendants.

HONORABLE JEROME B. SIMANDLE

Civil Action Nos. 14-1078 (JBS/KMW) 14-2982 (JBS/KMW) 14-3168 (JBS/KMW) 14-3306 (JBS/KMW) 14-3996 (JBS/KMW) 14-4307 (JBS/KMW) 14-4508 (JBS/KMW) 14-4671 (JBS/KMW) 14-5537 (JBS/KMW) 14-5876 (JBS/KMW) 14-5878 (JBS/KMW) 14-6158 (JBS/KMW) 14-6397 (JBS/KMW) 14-6398 (JBS/KMW) 14-6890 (JBS/KMW) 14-7105 (JBS/KMW) 14-7106 (JBS/KMW) 14-7252 (JBS/KMW) 14-7405 (JBS/KMW) 14-8074 (JBS/KMW) 14-8077 (JBS/KMW) 15-161 (JBS/KMW) 15-1585 (JBS/KMW) 15-1716 (JBS/KMW)

SCHEDULING ORDER REGARDING
PLAINTIFF'S MOTIONS FOR TRO AND
PRELIMINARY INJUNCTION

Plaintiff,

v.

INTAS PHARMACEUTICALS LIMITED, ACCORD HEALTHCARE, INC., and HETERO LABS LIMITED,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL INC., SUN PHARMA GLOBAL FZE, SUN PHARMA USA, SUN PHARMACEUTICALS INDUSTRIES, INC., and CARACO PHARMACEUTICAL LABORATORIES,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

MYLAN, INC., MYLAN
PHARMACEUTICALS INC., and
MYLAN LABORATORIES LIMITED,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

TORRENT PHARMACEUTICALS
LIMITED, INC., TORRENT PHARMA
INC., and HETERO LABS LIMITED,

Defendants.

Plaintiff,

v.

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US INC., PRINSTON PHARMACEUTICAL INC., and SOLCO HEALTHCARE U.S., LLC,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

AJANTA PHARMA LIMITED and AJANTA PHARMA USA INC.,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

INTAS PHARMACEUTICALS LIMITED, ACCORD HEALTHCARE, INC., and HETERO LABS LIMITED,

Defendants.

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES
LTD., SUN PHARMA GLOBAL INC.,
SUN PHARMA GLOBAL FZE, SUN
PHARMA USA, SUN PHARMACEUTICALS
INDUSTRIES, INC., and CARACO
PHARMACEUTICAL LABORATORIES,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

LUPIN LIMITED, LUPIN ATLANTIS HOLDING SA, LUPIN PHARMACEUTICALS, INC., and HETERO LABS LIMITED

Defendants.

Plaintiff,

v.

ACTAVIS ELIZABETH LLC, ACTAVIS, INC., ACTAVIS PLC, JUBILANT LIFE SCIENCES LIMITED, JUBILANT GENERICS LIMITED, and JUBILANT LIFE SCIENCES (USA) INC.,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS USA and CADILA HEALTHCARE LIMITED

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

ALEMBIC PHARMACEUTICALS
LIMITED, ALEMBIC LIMITED,
ALEMBIC GLOBAL HOLDING SA, and
ALEMBIC PHARMACEUTICALS INC.,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

APOTEX CORP., APOTEX INC., APOTEX PHARMACHEM INC., and HETERO LABS LIMITED,

Defendants.

Plaintiff,

v.

SCIEGEN PHARMACEUTICALS INC. and BACTOLAC PHARMACEUTICAL, INC.,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

HETERO DRUGS LIMITED, HETERO LABS LIMITED, and HETERO USA, INC.

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS INDIA PVT. LTD., MSN PHARMACHEM PVT. LTD., and MSN LABORATORIES PVT. LTD.,

Defendants.

OTSUKA PHARMACEUTICAL CO., LTD.,

Plaintiff,

v.

SANDOZ INC., SANDOZ PRIVATE LTD., and SANDOZ INTERNATIONAL GMBH,

Defendants.

These cases filed under the Hatch-Waxman Act pursuant to 35 U.S.C. §§ 271, 281, naming defendants which have filed Abbreviated New Drug Applications [ANDA's] before the Food and Drug Administration, came before the Court at a conference before the undersigned and the Honorable Karen M. Williams on March 16, 2015 upon Plaintiff's proposal to file motions for temporary restraining order and preliminary injunction with regard to the prospect of at-risk launches by as many as two-dozen Defendants that may occur on or after April 20, 2015 relating to aripiprazole, also known as Abilify; and

The Court having heard arguments of counsel and determining for reasons stated at the conference upon the record that the following procedures will (1) give each defendant due notice of the basis on which a TRO and preliminary injunctive relief is sought, (2) enable development of a suitable record in the shortest feasible time period upon which multiple TRO and preliminary injunction motions can be decided, (3) place the burden on Plaintiff to demonstrate why a TRO and preliminary injunction are warranted as to each defendant, (4) recognize that Plaintiff's supporting papers as to a particular defendant must be sufficiently specific and proportional to the information that Plaintiff, with the exercise of due diligence, has gained about the defendant's product, (5) avoid unnecessary

adjudication by permitting defendants which do not intend to launch at risk in the near future to so indicate and thereby opt out of this injunctive motion practice, while (6) observing the principle that the defendants will not be required to give notice of intent to launch at risk, all while (7) enabling argument and determination of such TRO applications by April 20, 2015.1

IT IS this <u>17th</u> day of <u>March</u>, 2015 hereby ORDERED:

1. That Plaintiff shall file its intended motion for TRO and preliminary injunction against each Defendant it seeks to preclude from at-risk launch, not later than March 19, 2015.

Plaintiff's supporting papers shall be as complete as possible, taking into account the time since filing the Complaint and the information available to Plaintiff with due diligence, and explaining the absence of more complete information in support of the motion. Cross-referencing to briefs and supporting

¹ On the record on March 16, 2015, counsel for Plaintiff stated Plaintiff's intention to file an additional action today, March 17, 2015. In the event that occurs, the Court would request that Plaintiff immediately serve a copy of this Order and that any briefing in the new action be submitted in accordance with this Scheduling Order, if possible

documents in and among related cases, such as by incorporation by reference, is permitted to avoid redundancy.²

- 2. Not later than March 27, 2015, a Defendant shall file its opposition brief and supporting materials. Alternatively, a Defendant may opt out of the motion practice not later than March 27, 2015 by filing, in lieu of opposition, a statement that Defendant does not intend to launch its aripiprazole product before June 20, 2015; in the case of such timely optout, the motions for TRO and preliminary injunctive relief against that Defendant will be dismissed without prejudice to renewal, and that Defendant will be deemed precluded from launching before June 20, 2015 unless otherwise ordered by the Court.
- 3. Plaintiff's reply papers in further support of the motions as to the remaining Defendants shall be filed not later than <u>April 2, 2015</u>. Such replies may amplify upon arguments previously made while avoiding introduction of new arguments.

 Again, cross-referencing to briefs and supporting documents in and among related cases is permitted.

² Plaintiff may, for example, file a Master Brief and adopt the portion or portions thereof that apply to a particular Defendant or Defendants, so long as Plaintiff is clear and specific about what it asserts against each Defendant.

- 4. To the extent that Plaintiff's reply amplifies upon earlier arguments previously made, a Defendant may, without further leave of Court, 3 submit a sur-reply by letter-brief of not more than five (5) pages not later than April 6, 2015.
- 5. The Court will convene a pre-TRO-hearing telephone logistics conference with counsel for Plaintiff and for the then-remaining Defendants only, on Tuesday, April 7, 2015 at 10:00 A.M., and Plaintiff's counsel are requested to arrange the conference call.
- 6. The hearing upon motions for a Temporary Restraining Order will be convened on <u>Friday, April 10, 2015 at Noon</u> before the undersigned. The Court will endeavor to decide the TRO applications before April 20, 2015.
- 7. The Court has set Monday, May 4, 2015 at 10:00 A.M. as the time of the Preliminary Injunction Hearing. The Court anticipates setting a schedule for any further preliminary injunction submissions at or after the April 10th TRO hearing.
- 8. The parties may obtain limited, expedited discovery necessary to obtain evidence for the preliminary injunction motion, and counsel shall extend mutual cooperation in this

³ This deadline was not explicitly discussed at the conference and it has been added in recognition that the need for a surreply may be expected, given the importance placed upon the reply brief in focusing Plaintiff's position.

regard. A dispute about the scope or timing of such limited, expedited discovery may, after personally conferring as required by L. Civ. R. 37.1(a)(1), be presented to Judge Williams by letter requesting a telephone conference and detailing such dispute.

9. In order to protect confidential and/or proprietary information and to expedite this process, the parties may file unredacted copies of their respective submissions in connection with the motion for TRO and preliminary injunction under seal, without contemporaneously filing motions to seal under Local Civil Rule 5.3.4 However, any submission filed under seal must be accompanied by a public version of the submission that redacts only the confidential and/or proprietary information. For purposes of this procedure, confidential and/or proprietary information is deemed to include but not be limited to information that a party has designated as confidential in good faith, under the provisions of a Stipulated Confidentiality Order herein, and without relinquishing a party's right to dispute such designation at a later date. In the event

⁴ Unredacted submissions must, of course, be exchanged by the parties implicated in the briefing, subject to the protective order entered in the respective case or the default protective order set forth in the Local Patent Rule 2.2.

Case 2:24-cv-07791-BRM-CLW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 13 of 13 Case 1:14-cv-01078-JBS-KMW Document 100-2 Filed 01/23/25 Page 12 of 12 PageID: 788

other submissions from another related case, Plaintiff must assure that the referenced information is available to the Defendant (i.e., that it does not include the confidential information of another Defendant that has been filed under seal in the referenced case).

s/ Jerome B. Simandle

JEROME B. SIMANDLE Chief U.S. District Judge